K081227 (pg. 1 of 3)

7.0 510 (K) Summary of Safety and Effectiveness

July 14, 2008

1. Submission Applicant & Correspondent:

JUL 22 2008

Name:	Osteotech, Inc.
Address:	51 James Way
	Eatontown, NJ 07724
Phone No.:	(732) 542-2800
Contact Person:	Chris Talbot

2. Name of Product:

Trade/Proprietary/Model Name:	PLEXUR M ™
Common or Usual Name:	Bone Void Filler
Classification Name:	Resorbable Bone Void Filler

3. Devices to Which New Product is Substantially Equivalent:

PLEXUR M is substantially equivalent, for the purpose of this 510(k), to other devices that have received 510(k) clearance for similar indications for use.

4. Device Description:

PLEXUR M is a bone void filler product that contains, as a key constituent, processed human bone particles that are mixed with resorbable/biodegradeable non-tissue components. It is intended to be heated at the time of use, whereupon it becomes moldable, thus allowing the surgeon to pack it into the implant site or shape it to accommodate variations in the geometry and size of the particular implant site. As it cools down, the PLEXUR M returns to its normal hardened/rigid state and remains this way at body temperature. The surgeon may further shape, cut or grind PLEXUR M in the hardened state using conventional surgical instruments.

PLEXUR M is packaged/provided for single use in a sterile form. PLEXUR M is resorbed/remodeled and is replaced by host bone during the healing process. A compact, single use heater is available as a means to heat the PLEXUR M at the time of use to make it pliable. Alternatively, PLEXUR M may be heated in a water bath.

5. Intended Use/Indications

PLEXUR M is intended for use in filling bony voids or gaps of the skeletal system (i.e. extremities and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. In addition, Plexur M may be used in conjunction with autograft as a bone void filler in the spine. PLEXUR M is resorbed/remodeled and is replaced by host bone during the healing process.

6. Technical Comparison

PLEXUR M is substantially equivalent to one or more of the predicate devices with respect to materials. PLEXUR M contains human allograft bone tissue, as does one or more of the predicate devices. PLEXUR M also contains resorbable polymer of the same type as those in one or more of the predicate devices. Also, like one or more of the predicate devices, PLEXUR M is provided sterile in various sizes that, upon heating (using a compact, single use sterile heater to be marketed by Osteotech), it is made moldable and can be cut or shaped by the user into various shapes or sizes. It may be further shaped by the surgeon in its hardened state using conventional surgical instruments.

7. Performance Data

The results of studies in animal showed that PLEXUR M supports bone in-growth and new bone formation to an extent at a rate at least comparable to predicate devices.

8. Viral Inactivation

In the production of PLEXUR M, the allograft bone is subjected to processing steps that have been shown to inactivate viruses, including HIV, hepatitis B and C and CMV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Osteotech, Inc.
% Mr. Chris Talbot
51 James Way
Eatontown, NJ 07724

JUL 22 2008

Re: K081227
Trade/Device Name: PLEXUR M™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: April 29, 2008
Received: April 30, 2008

Dear Mr. Talbot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 Indications for Use Statement

510(k) Number: K081227

Device Name: PLEXUR M

Indications for Use: PLEXUR M is intended for use in filling bony voids or gaps of the skeletal system (i.e. extremities and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. In addition, Plexur M may be used in conjunction with autograft as a bone void filler in the spine. PLEXUR M is resorbed/remodeled and is replaced by host bone during the healing process.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081227